DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
3426 6d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 3003212883

August 18, 2003

Joe A. and Kimberly L. Sozinho, Owners
Westside Dairy
15959 South Marks Ave.
Caruthers, CA 93609

WARNING LETTER

Dear Joe and Kimberly Sozinho:

Tissue residue reports received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residue in cows that originated from your dairy. As a follow-up to USDA's finding, our investigator performed an inspection of your dairy operation July 15 - 18, 2003. This inspection revealed serious violations of Sections 402(a)(2)(C)(ii), 402(a)(4) and 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). .

On February 26, 2003, you consigned a dairy cow, subsequently identified with [redacted] back tag numbe[redacted] last four digits, for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 447015) collected from that animal identified the presence of the drug oxytetracycline in the muscle at 42.88 ppm and in the kidney at 71.17 parts per million (ppm).

In addition, on March 10, 2003 you consigned a dairy cow, subsequently identified with [redacted] back tag number[redacted], last four digits, for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 447038) collected from that animal identified the presence of the drug oxytetracycline in the muscle at 36.71 ppm , in the liver at 32.92 ppm, and in the kidney at 28.31 parts per million (ppm).

Presently, the tolerance level for the sum of tetracycline residues, including oxytetracycline, in the tissue of cattle is 2 ppm in the muscle, 6 ppm in the liver, and 12 ppm in the kidney (Title 21 Code of Federal Regulations (CFR), Part 556.500). Your use of oxytetracycline in these animals resulted in the illegal drug residue found in the kidney. A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigators noted the following:

1. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling. For example, the labeling for Durvat Brand Duramycin-100 (Oxytetracycline HCl) prescribes the drug for intravenous administration. You are infusing this drug via intrauterine administration. In addition, you are failing to follow the labeled directions for IBA Brand Penicillin G procaine and Pharmacia and Upjohn Brand Predef 2X (Isoflupredone acetate).

2. You lack an adequate inventory/accountability system for determining the quantities of drugs used to medicate your cows and calves.

3. You fail to maintain complete medication treatment and culling records on the dairy cows. For example, your treatment records fail to include the drug preslaughter time and the person administering the drugs. In addition, you transfer the information from a small notebook into a large notebook, subsequently discarding the original small notebook. Our review of these records found instances in which you failed to include the ear tag numbers of culled animals in the large notebook and failed to record the sale of an animal on July 11, 2003 in the large notebook.

You are adulterating Durvat Brand Duramycin-100 within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. The manufacturer's label prescribes intravenous administration only. Your are administering the drug intrauterine. Your failure to follow the prescribed labeling presents a possibility that illegal residues will occur.

Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Dennis K. Linsley
District Director
San Francisco District

cc: James Davis, DVM
Lemoore Animal Clinic
526 Armstrong
Lemoore, CA 93245